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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,251	03/21/2001	Robert W. Stadler	P-8777	5575

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EXAMINER

OROPEZA, FRANCES P

ART UNIT PAPER NUMBER

3762

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/814,251

Applicant(s)

STADLER ET AL. *CA*

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The claims of record were successfully amended to overcome the art of record, hence a new grounds of rejection is established for the pending claims.

Claim Rejections - 35 USC § 112

2. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 appears redundant of claim 1 (iv). Cancellation of claim 6 is suggested. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. Claims 1, 3, 4 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Gunderson (US 5330508). Gunderson discloses an apparatus to sense depolarizations, measure depolarization intervals, store the intervals, detect tachyarrhythmia, and discriminate between the tachycardia and fibrillation using sorting of intervals into bins, counting the number of intervals per bin, defining the threshold criteria point and triggering therapy if the criteria point is met (Abstract; col. 2 @ 63 – col. 3 @ 25).

As to claims 3 and 4, the threshold number is read as a predetermined number of bins that exceed a ratio (percentage) of intervals attaining at least a predetermined threshold. The threshold number increases as an inverse function of the length of the interval (col. 2 @ 67 – col. 3 @ 7).

As to claim 7, the apparatus distinguishes between VT and VF and provides appropriate therapy (col. 3 @ 6-16).

As to claim 8, the apparatus distinguishes between VT and AF and provides appropriate therapy (col. 3 @ 17-25).

As to claim 9, the threshold number is variable based on the detected arrhythmia (col. 4 @ 19-22; col. 10 @ 62 – col. 11 @ 8; col. 12 @ 9-21).

Claim Rejections - 35 USC § 103

4. It appears figures 8 a-c were not included in the application as originally filed. Figure 8a is described in the specification as a scatter plot apparently related to claim 10, hence the following rejection reflects the Examiner's best understanding of claims 10 and 11.

Claims 5, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunderson (US 5330508) in view of Rossing (US 5464430). As discussed in paragraph 3 of this action, Gunderson discloses the claimed invention except for: 1) the threshold value increasing as a function of the 75th percentile of the length of the intervals of a predetermined number of intervals (claim 5), and 2) the threshold value decreasing as a function of the 75th percentile of the length of the intervals of a preceding series of depolarizations (claims 10 and 11).

Rossing teaches arrhythmia discrimination:

1) using a threshold number varying as an increasing or decreasing function of the cycle lengths (intervals) for the purpose of defining different arrhythmias, and

2) using the 75th percentile cycle length of a preceding sequence of depolarizations as the measurement metric for the purpose of providing a stringent criteria to judge cardiac rhythms and define specific arrhythmias.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the threshold number varying as an increasing or decreasing function of the cycle length and to have used the 75th percentile cycle length as the measurement metric in the Gunderson system in order to distinguish between the various tachyarrhythmias so appropriate therapy can be provided to the patient (col. 1 @ 10-15; col. 2 @ 34-63; col. 4 @ 3-17).

Drawings

5. Figures 6, 7, and 8 a-c are referenced in the specification, but these figures were apparently not included in the application as originally filed. These figures should be submitted for potential inclusion in the application, assuming no new matter is presented, or reference to these figures should be deleted from the specification.

Statutory Basis for Rejections

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). The Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

3/7/03



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